Our Reference Numbers: 86-0482, 88-0172, 95-1301, 95-1302, 95-1303 and 95-1305

Mr. Patrick K. Smith
Allergy Laboratories, Inc.
P.O. Box 25492
Oklahoma City, OK 73126-0492

MAY 29 1997

Dear Mr. Smith:

The Supplements to your Product License Application for Allergenic Extracts to include the manufacture of Standardized Kentucky (June) Bluegrass (*Poa pratensis*) Pollen Extract (86-0482); Standardized Timothy Grass (*Phleum pratense*) Pollen Extract (88-0172); Standardized Meadow Fescue Grass (*Festuca elatior*) Pollen Extract (95-1301); Standardized Sweet Vernal Grass (*Anthoxanthum odoratum*) Pollen Extract (95-1302); Standardized Orchard Grass (*Dactylis glomerata*) Pollen Extract (95-1303); and Standardized Redtop Grass (*Agrostis alba*) Pollen Extract (95-1305); with potencies of 100,000 and 10,000 Bioequivalent Allergy Units (BAU)/ml, and 100 BAU/ml diluted from 10,000 BAU/ml, have been approved based upon the information submitted.

You are requested to submit samples of each future lot of the Standardized Grass Pollen Extracts together with the lot release protocols showing the results of all applicable tests and indicating the source material suppliers and the lot numbers of the grass pollen source materials. No lot of these products shall be distributed until notification of release is received from the Center for Biologics Evaluation and Research (CBER).

The interim dating period for the above cited Standardized Grass Pollen Extracts with potencies of 10,000 BAU/ml and 100,000 BAU/ml containing 50% glycerol (v/v) shall be 36 months from the date of manufacture when stored at 2-8°C. This interim dating period is based on 12 months of real time stability data submitted and the 36 months dating period (manufacturer's storage) allowed for glycerinated non-standardized extracts (21 CFR 610.53). The provisional dating period for 100 BAU/ml extract, containing less than 50% glycerin, shall be 12 months from the date of manufacture when stored at 2-8°C. The expiration date of the 100 BAU/ml product shall not exceed the final expiration date of the 10,000 BAU/ml concentrate. We acknowledge your commitment dated October 11, 1995, to continue the stability study (based on your approved stability protocol) for the remainder of the 36 months. Stability data supporting the 36 month dating period

should be submitted when available. Any requests to extend the dating period beyond 36 months will require the submission of a Supplement to your Product License Application. If at any time the sample fails to meet the specifications outlined in your stability protocol, you are requested to inform CBER immediately and you are reminded that these failed lots could be subject to a recall.

We also acknowledge your written commitment dated September 12, 1996, to perform a Phase 4 post-marketing study of these Standardized Grass Pollen Extracts in order to obtain additional information regarding the products' risks, benefits, and optimal use.

It is requested that adverse experience reports for Standardized Grass Pollen Extracts be submitted in accordance with the adverse experience reporting requirements for licensed biological products pursuant to Title 21 of the Code of Federal Regulations Part 600.80 and that distribution reports be submitted as described in 21 CFR Part 600.81.

Please submit three (3) copies of final printed labeling at the time of use accompanied by Part II of FDA 2567 with completed implementation information. In addition, you may wish to submit your proposed introductory advertising and promotional campaign. If so, please submit three (3) copies of the proposed material in draft form with Part I of FDA Form 2567 to the CBER, Advertising and Promotional Labeling Staff (APLS), HFM-202, 1401 Rockville Pike, Rockville, MD 20852-1448. Promotional claims should be consistent with and not contrary to approved labeling. No comparative claims or claim of superiority over other similar products should be made unless data to support such claims are submitted to and approved by the CBER. Final copies of advertising and promotional materials should be submitted at the time of use with Part II of FDA Form 2567 to APLS. Please include copies of the approved labeling with your proposed or final copy of advertising and promotional materials submitted to CBER.

This information will be included in your Product License Application File.

Sincerely yours,

M. Carolyn Hardegree, M.D.
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research